



Atty. Dkt. No. 056324-0129

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: R. Tyler WHITE et al.
Title: PROTEASE INHIBITOR PEPTIDES
Appl. No.: 10/076,604
Filing Date: 02/19/2002
Examiner: E. Slobodyansky
Art Unit: 1652

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/201,715, filed 12/01/1998. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

08/24/2004 EAREGAY1 00000006 10076604

01 FC:1806

180.00 0P



TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date August 23, 2004

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5446
Facsimile: (202) 672-5399

Matthew E. Mulkeen
Registration No. 44,250

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: August 23, 2004

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	10/076,604
Filing Date	02/19/2002
First Named Inventor	R. Tyler White
Group Art Unit	1652
Examiner Name	E. Slobodyansky
Attorney Docket Number	056324-0129

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A16	DENNIS, M. <i>et al.</i> , "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa", <i>J. of Biol. Chem.</i> , Vol. 269, No. 35, Sept. 2, pp. 22129-136, 1994.	
	A17	COLMAN, R., "Factor XII Activation and Inhibition In Inflammation", <i>Proteases, Protease Inhibitors and Protease-Derived Peptides</i> , pp. 125-43, 1993.	
	A18	SCOTT, C. <i>et al.</i> , "Kinetics of Inhibition of Human Plasma Kallikrein by a Site-Specific Modified Inhibitor Arg ¹⁵ -Aprotin: Evaluation Using a Microplate System & Comparison with Other Proteases", <i>Blood</i> , Vol. 69, No. 5 (May), 1987: pp. 1431-36.	
	A19	PATSON, P. <i>et al.</i> , "Reactivity of α_1 -Antitrypsin Mutants against Proteolytic Enzymes of the Kallikrein-Kinin, Complement, and Fibrinolytic Systems", <i>J. of Biol. Chem.</i> , Vol. 265, No. 18, pp. 10786-91, June 25, 1990.	
	A20	WEN, L. <i>et al.</i> , "Chemical Synthesis, Molecular Cloning, Overexpression, and Site-Directed Mutagenesis of the Gene Coding for Pumpkin (<i>Curcubita maxima</i>) Trypsin Inhibitor cMTI-V", <i>Protein Expression and Purification</i> 4, pp. 215-22 (1993).	
	A21	PEDERSEN, L. <i>et al.</i> , "The Corn Inhibitor of Blood Coagulation Factor XIIa, Crystallization and Preliminary Crystallographic Analysis", <i>J. Mol. Biol.</i> (1994) 236, pp. 385-87.	
	A22	PONTE, P. <i>et al.</i> , "A New A4 Amyloid mRNA contains a domain homologous to serine proteinase inhibitors", <i>Nature</i> , Vol. 331, pp. 525-527, February 11, 1988.	
	A23	TANZI, R. <i>et al.</i> , "Protease Inhibitor Domain Encoded by an Amyloid Protein Precursor mRNA associated with Alzheimer's Disease", <i>Nature</i> , Vol. 331, pp. 528-530, Feb. 11, 1988.	
	A24	JOHNSTONE, E. <i>et al.</i> , "Alzheimer's Disease Amyloid Peptide is Encoded by Two Exons and Shows Similarity to Soybean Trypsin Inhibitor", <i>Biochem. & Biophys. Res. Comm.</i> , Vol. 163, No. 3, pp. 1248-1255, Sept. 29, 1989.	
	A25	WENZEL, H. <i>et al.</i> , "Semisynthetic Conversion of the Bovine Trypsin Inhibitor (Kunitz) into an Efficient Leukocyte-Elastase Inhibitor by Specific Valine for Lysine Substitution in the Reactive Site", <i>Chem. of Peptides and Proteins</i> , Vol. 3, pp. 105-117, (1986).	
	A26	NORRIS, K. <i>et al.</i> , "Aprotinin and Aprotinin Analogues Expressed in Yeast", Walter de Gruyter & Co., pp. 37-42, May 1990.	
	A27	PERONA, J.J. <i>et al.</i> , "Crystal Structures of Rat Anionic Trypsin Complexed with Protein Inhibitors APPI and BPTI", <i>J. Mol. Biol.</i> (1993) 230:919-933.	
	A28	SINHA S. <i>et al.</i> , "Conversion of the Alzheimer's β -Amyloid Precursor Protein (APP) Kunitz domain into a Potent Human Neutrophil Elastase Inhibitor", <i>J. of Biol. Chem.</i> , Vol. 266, No. 31, (1991), pp. 21011-13.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number 0774 Substitution for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: August 23, 2004 (Use as many sheets as necessary)				Complete if Known	
AUG 23 2004 TRADEMARK EXAMINER'S OFFICE				Application Number	10/076,604
				Filing Date	02/19/2002
				First Named Inventor	R. Tyler White
				Group Art Unit	1652
				Examiner Name	E. Slobodyansky
Sheet 3 of 3				Attorney Docket Number	056324-0129

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.